

We Claim:

1. A pharmaceutical composition comprising an effective amount of amlodipine maleate and at least one pharmaceutically acceptable excipient wherein said composition has a pH within the range of 5.5- 7.0.

2. The composition according to claim 1, wherein said composition has a pH of about 6.0 - 7.0.

3. The composition according to claim 1, wherein said composition is in solid form.

4. The composition according to claim 1, wherein said excipient is calcium phosphate or microcrystalline cellulose.

5. The composition according to claim 4, wherein said composition comprises calcium phosphate and microcrystalline cellulose.

6. The composition according to claim 4, wherein said excipient is calcium hydrogen phosphate.

7. The composition according to claim 4, wherein said excipient is microcrystalline cellulose.

8. The composition according to claim 1, wherein said composition further comprises an acidic pH adjusting agent.

9. The composition according to claim 1, wherein said composition is in the form of a tablet.

10. The composition according to claim 9, which further comprises an outer layer surrounding said tablet.

11. The composition according to claim 1, wherein said composition is in the form of a capsule.

12. The composition according to claim 1, wherein said amount of amlodipine maleate corresponds to 1.0 to 25 mg of amlodipine free base.

13. The composition according to claim 12, wherein said amount of amlodipine maleate corresponds to 1.25, 2.5, 5 or 10 mg of amlodipine free base.

14. A method for treating or preventing angina, hypertension, or heart failure, which comprises administering to a patient in need thereof an effective amount of the composition according to claim 1.

SUB  
A2  
15. A process for making the composition according to claim 1, which comprises mixing amlodipine maleate and at least one pharmaceutically acceptable excipient to form a mixture having a pH within the range of 5.5 to 7.

16. A process, which comprises:  
mixing amlodipine maleate and at least one pharmaceutically acceptable excipient to form a mixture having a pH of 5.5-7.0.

17. The process according to claim 16, which further comprises compressing said mixture into a tablet.

18. The process according to claim 16, which further comprises filling capsules with said mixture to form a pharmaceutical dosage form.

19. The process according to claim 16, wherein said mixing is carried out by wet granulation.

20. The process according to claim 16, wherein said mixing is carried out by a dry method.

09938816-082701

21. The process according to claim 20, wherein said amlodipine maleate is mixed as solid particles having an average particle size of at least 100 microns with said excipient.

22. A tablet made according to the process of claim 16.

23. A process, which comprises:  
mixing solid particles of amlodipine maleate, having an average particle size of at least 20 microns, with a pharmaceutically acceptable excipient to form a mixture.

24. The process according to claim 23, which further comprises filling capsules with said mixture to form a pharmaceutical dosage form.

25. The process according to claim 23, which further comprises compressing said mixture to form a tablet.

26. The process according to claim 23, wherein said average particle size is at least 100 microns.

27. The process according to claim 23, wherein said mixture is blended with one or more appropriate excipients so as to have a pH within the range of 5.5 to

7.

Ad  
A3

00938816-032701